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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/082,247	05/20/1998	JAMES G. NADEAU	P-2821RI	2478

909            7590            05/09/2002  
PILLSBURY WINTHROP, LLP  
P.O. BOX 10500  
MCLEAN, VA 22102

EXAMINER
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TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637  
DATE MAILED: 05/09/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.



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7590                    07/31/2002

David W. Hight  
Becton, Dickinson & Company  
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Franklin Lakes, NJ 07417

[REDACTED] EXAMINER

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/082,247	NADEAU ET AL.
	Examiner Joyce Tung	Art Unit 1637

FILE

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 February 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-20 is/are allowed.
- 6) Claim(s) 21-42 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 May 1998 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: *Detailed Action*.

### *Reissue Applications*

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

1. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.
2. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.121(b).
3. The amendment filed 2/28/2002 has been entered.
4. The rejection of claims 21-42 under 35 U.S.C. §112, first paragraph (new matter) is withdrawn because of the argument.
5. Claims 21-42 under 35 U.S.C. §112, first paragraph (enablement) remain rejected.

As indicated in the response filed 10/05/2001, Applicants and the Examiner have exchanged views regarding certain passage in the specification relating to disclosure about high levels of background signal generated by certain primer-based amplification and detection method. The specification provides guidance only with regard to the signal primer used as the primer without being function as an amplification primer with the SDA reaction (See column 6, lines 25-27 of the specification). The working examples are presented only with regard to use the signal primer in SDA reaction (See column 10, example 2). The results of experiments involving using the signal primer as claimed with any primer-based amplification is not

predictable because the method steps of SDA reaction as disclosed in the specification are different from the method steps of the conventional primer based amplification as disclosed in the reference of Mullis et al. (4,965,188) and there is no inference that the signal primer as claimed can be used with any primer based amplification resulting the same. The level of skill in molecular biology is high. Therefore, one of ordinary skill in the art would be subject to undue experimentation in using the signal primer as claimed to any kind of primer based amplifications.

In addition, the language for the characteristic of the signal primer is conflicting with the language in step (b) of claims 21 and 29 as set forth in section 9(a) below. Thus, the rejection is maintained.

#### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 21-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recited element of the amended claims is not supported in the original disclosure. There is no description regarding how to concurrently generate a secondary amplification product and an amplification in a primer based nucleic acid amplification reaction with a signal primer wherein the signal primer may not function as an amplification primer. The only example is that the signal primer used as the primer without being function as an amplification primer is used with the SDA reaction (See column 6, lines 25-

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27 of the specification). There is no mention of PCR coupled amplification only SDA coupled amplification in the specification. Therefore, the amended claims are not supported in the original disclosure and 35 U.S.C. 112, first paragraph required that claim language be supported in the specification.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 21-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 21-42 are vague and indefinite because of the language “a characteristic of said signal primer is that it may not function as an amplification primer”. The language indicates that the signal primer may not function as an amplification primer, but in step (b) of claims 21 and 29, the language indicates that the signal primer is extended to produce the signal primer extension product. Thus, the language appears confusing. Clarification is required.

*Drawings*

10. Applicants are required to file drawings without the patent information on the top of the drawings.

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11. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

April 30, 2002



GARY BENZION, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600